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10/080,130

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,130	02/19/2002	Romano Deghenghi	87264-300	9172
28765	7590	07/28/2005	EXAMINER	
WINSTON & STRAWN LLP 1700 K STREET, N.W. WASHINGTON, DC 20006				VANIK, DAVID L
ART UNIT		PAPER NUMBER		
		1615		

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<i>16</i> <b>Office Action Summary</b>	Application No.	Applicant(s)
	10/080,130	DEGHENGHI ET AL.
	Examiner David L. Vanik	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 21 January 2005.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,2,6-13,17-29 and 32-59 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1,2,6-13,17-29 and 32-59 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of the amended claims and arguments filed on 1/21/2005. It should be noted that this application was transferred from examiner James Spear to examiner David Vanik. The examiner directs applicant's attention to section 2421 of the MPEP for the rules outlining sequences.

#### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-2, 7-11, 40, 53, 58 drawn to a method of preparing a suspension by associating AC-D-Nal-DCPa-D-Pal-Ser-Tyr-D-Hci-Leu-Ilys-Pro-D-Ala-NH<sub>2</sub> with a counter ion, classified in class 514, subclass 484
  - II. Claim 6, drawn to a method of preparing a formulation by associating a GnRH antagonist with a counter-ion, classified in class 514, subclass 241.
  - III. Claims 12-13, 18-26, 32-39, 42, 45-52, 55, 59 drawn to a composition comprising a peptide and a counter-ion, classified in multiple classes and subclasses including class 424, subclass 489.
  - IV. Claim 17, drawn to a composition comprising a GnRH antagonist and a counter-ion, classified in class 424, subclass 177.
  - V. Claim 27-29, 41, 43, 44, 54, 56-57, drawn to a method of preparing a lyophilized composition comprising a peptide and a counter-ion, classified in class 514, subclass 484.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II, V and Inventions III, IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the products as claimed can be prepared in the absence of a counter-ion. In addition, there are various other counter-ions suitable for use in the instant invention. As such, a reference anticipating one group of inventions would not necessarily render the other inventions obvious.
  
3. Inventions I and II are unrelated to one another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Inventions I and II have different modes of operation and effects. While Invention I is drawn to a method of preparing a suspension comprising a peptide of the formula AC-D-Nal-DCPa-D-Pal-Ser-Tyr-D-Hci-Leu-Ilys-Pro-D-Ala-NH<sub>2</sub>, Invention II is drawn to a method of preparing a suspension comprising a GnRH antagonist, a much broader class of compounds. The scope of these two inventions is sufficiently distinct to warrant restriction. As such, a reference anticipating one group of inventions would not necessarily render the other inventions obvious.

4. Inventions I and V are unrelated to one another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Inventions I and V have different modes of operation and effects. While Invention I is drawn to a method of preparing a **suspension** comprising a peptide of the formula AC-D-Nal-DCPa-D-Pal-Ser-Tyr-D-Hci-Leu-Ilys-Pro-D-Ala-NH<sub>2</sub>, Invention V is drawn to a method of preparing a **lyophilized** peptide corresponding to AC-D-Nal-DCPa-D-Pal-Ser-Tyr-D-Hci-Leu-Ilys-Pro-D-Ala-NH<sub>2</sub>. As such, a reference anticipating one group of inventions would not necessarily render the other inventions obvious.

5. Inventions II and V are unrelated to one another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Inventions I and V have different modes of operation and effects. While Invention I is drawn to a method of preparing a **suspension** comprising a GnRH antagonist, Invention V is drawn to a method of preparing a **lyophilized** peptide corresponding to AC-D-Nal-DCPa-D-Pal-Ser-Tyr-D-Hci-Leu-Ilys-Pro-D-Ala-NH<sub>2</sub>. As such, a reference anticipating one group of inventions would not necessarily render the other inventions obvious.

6. Inventions III and IV are unrelated to one another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the compositions of Inventions III and IV have different functions and effects. While Invention III is drawn to a composition comprising a peptide of the formula Ac-D-Nal-DCPa-D-Pal-Ser-Tyr-D-Hci-Leu-Ilys-Pro-D-Ala-NH<sub>2</sub> together with a counter-ion, Invention IV is drawn to a composition comprising a GnRH associated with a counter-ion. As such, a reference anticipating one group of inventions would not necessarily render the other inventions obvious.

7. Searching the inventions of Groups I – V together would impose a search burden on the examiner. In the instant case, the search of distinct peptide and antagonist compositions and methods of preparing said compositions imposes a search burden on the examiner.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. Because these inventions are distinct for the reasons given above and the search required for each subset of Groups I – V are not required for one another, restriction for examination purposes as indicated is proper.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. **In the event that applicant elects Groups I or III, the following election of species is required.** This application contains claims directed to the following patentably distinct species of peptides:

- (a) Ac-D-Nal-DCPa-D-Pal-Ser-Tyr-D-Hci-Leu-Ilys-Pro-D-Ala-NH<sub>2</sub>
- (b) Vapreotide
- (c) Octreotide
- (d) Lanreotide
- (e) SOM 230

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 7, 12, 18 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. **In the event that applicant elects Groups I, III, or V, the following species election is required.** This application contains claims directed to the following patentably distinct species of counter-ions:

- (a) trifluoromethanesulfonic acid
- (b) benzenesulfonic acid
- (c) trifluoroacetic acid
- (d) sulfuric acid

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 7, 12, and 18 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. Applicant's agent, Jeffrey Wolfson, was contacted at telephone number (202) 282-5000 on 7/22/2005 concerning this election requirement. Mr. Wolfson was informed that, due to the complexity of the action, the reaction was submitted in writing.

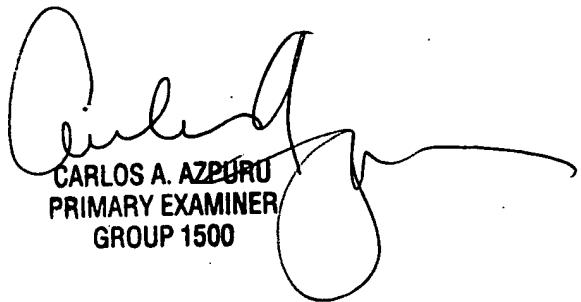
***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.  
Art Unit 1615



CARLOS A. AZPURU  
PRIMARY EXAMINER  
GROUP 1500



7/22/08